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EXAMINER

MILLER, CHERYL L

ART UNIT	PAPER NUMBER
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3738

DATE MAILED: 07/08/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No. 10/048,112	Applicant(s) BERCOVY, MICHEL	
	Examiner Cheryl Miller	Art Unit 3738	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 08 April 2004.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 7-21 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 7-21 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 08 April 2004 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☒ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Response to Arguments

Applicant's arguments with respect to claims 1-6 have been considered but are moot in view of the new ground(s) of rejection.

However, since the same reference (Walker, US 5,330,533) has been used in the current rejection, the examiner will respond to applicant's arguments. Applicant has argued that Walker does not disclose 1. a spiral curve in a sagittal plane, and 2. an absence of any discontinuities, sharp edges, or flats in the undulating curve of the prosthesis. The examiner disagrees.

Referring to figures 3b-3c of Walker, a prosthesis having components resembling a natural knee joint, however having a larger continuous femoral surface is shown, having in a sagittal plane, a spiral curve (non-spherical, non-constant radius, see col.2, lines 44-63; col.1, lines 34-41).

Although the focused embodiment of Walker discloses a spherical, constant radius curve in the sagittal plane (fig.4a-4b), Walker still does disclose an embodiment of a non-constant, spiral curve in the sagittal plane, shown in figures 3b and 3c. Even though disclosed as being disadvantageous, such an embodiment is taught and shown non-the less. Now referring to applicant's argument that Walker does not have an absence of discontinuities, sharp edges, or flats, the examiner disagrees. Because the applicant has claimed discontinuities, sharp edges, *or* flats, this limitation is in the alternative, therefore, a reference must have an absence of **only one** of the elements listed, to read on the claim. Also, applicant has claimed an absence or any discontinuities, or sharp edges in the undulating curve, which may be taken at any frontal cross-section, which Walker has many frontal cross-section's that would provide an absence of any discontinuities or sharp edges. Also, applicant has claimed, that the undulating curve following

Art Unit: 3738

the entire articular surface of the femoral component from its most frontal part to the rearmost part thereof. Therefore, only the femoral component requires an absence of discontinuities on the curve from front to back. Even if the applicant had claimed this for the undulating curve of the insert, the applicant has claimed the curve following the entire *articular* surface. The one small flat on the insert shown in Walker in fig.3c, is not part of the surface that articulates, therefore is not on the articular surface, and does not then, require the absence of any discontinuities, or sharp edges.

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 7-21 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter, which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. Claims 7, 15, and 18 recite that the femoral component and tibial component both may be formed of a material that may be ceramic. Femoral and tibial components made of ceramic were not found to be disclosed in the specification and are considered new matter. Claims 8-14, 16-17, and 19-21 depend upon claims 7, 15, and 18, and inherit all problems associated with the claim.

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 7-21 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 7 recites the limitation "said lateral condylar parts" in line 12. There is insufficient antecedent basis for this limitation in the claim. It is suggested to change "said lateral condylar parts" to recite --said lateral parts--. Also, it is noted that on line 4, tibial is misspelled "tribial". Claims 8-14 depend upon claim 7 and inherit all problems associated with the claim.

Claim 7 recites the limitation "the surface" in lines 13-14. There is insufficient antecedent basis for this limitation in the claim.

Claim 7 recites the limitation "the component" in line 18. There is insufficient antecedent basis for this limitation in the claim. It is suggested to change "the component" to recite --the femoral component--.

Claim 7 recites the limitation "the projecting part 9" in lines 18-19. There is insufficient antecedent basis for this limitation in the claim. It is suggested to change "the projecting part 9" to recite --the projecting central part 9--.

Claim 7 recites the limitation "the surfaces" in line 20. There is insufficient antecedent basis for this limitation in the claim.

Claim 7 recites the limitation "concave parts and convex parts" in line 23. There is insufficient antecedent basis for this limitation in the claim.

Claim 7 recites the limitation "the contact surfaces" in line 25. There is insufficient antecedent basis for this limitation in the claim.

Claim 7 recites the limitation "the condylar parts" in line 39. There is insufficient antecedent basis for this limitation in the claim. It is suggested to change "the condylar parts" to recite --the lateral parts--.

Claim 7 recites the limitation "the entire articular surface" in lines 41-42. There is insufficient antecedent basis for this limitation in the claim.

Also in claim 7, when referring to curve S1, which follows the femoral component, applicant has referred to the projecting central part 9 as part of the curve, which is inaccurate, and maybe should be the hollowed central part 10.

Claim 8 recites the limitation "the convex central projection" in lines 1-2. There is insufficient antecedent basis for this limitation in the claim.

Claim 8 recites the limitation "the hollowed lateral parts" in line 3. There is insufficient antecedent basis for this limitation in the claim.

Claim 9 recites the limitation "the hollowed lateral part 10" in line 2. There is insufficient antecedent basis for this limitation in the claim.

Claim 10 recites the limitation "central part" in line 5. There is insufficient antecedent basis for this limitation in the claim.

Claim 10 recites the limitation "the central part 10" in line 2. There is insufficient antecedent basis for this limitation in the claim.

Claim 10 recites the limitation "the condylar parts" in lines 1 and 4. There is insufficient antecedent basis for this limitation in the claim.

Claim 11 recites the limitation "the projecting part 9" in line 1. There is insufficient antecedent basis for this limitation in the claim. It is suggested to change "the projecting part 9" to recite --the projecting central part 9--.

Claim 11 recites the limitation "the hollowed part 10" in line 2. There is insufficient antecedent basis for this limitation in the claim. It is suggested to change "the hollowed part 10" to recite --the hollowed central part 10--.

Claim 11 recites the limitation "the intercondylar space" in line 2. There is insufficient antecedent basis for this limitation in the claim.

Claim 12 recites the limitation "the concave parts" in line 8 and "the convex parts" in line 10. There is insufficient antecedent basis for this limitation in the claim.

Claims 15-21 contain similar errors. When introducing a limitation, especially when defining a limitation with a reference numeral, applicant should be consistent throughout the claims with the terminology they introduced with. Multiple errors exist.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 7-21 are rejected under 35 U.S.C. 102(b) as being anticipated by Walker (US 5,330,533, cited in previous office action). Referring to claims 7, 10-12, 15, 18, and 21, Walker discloses a knee prosthesis comprising a femoral component (fig.3b), a tibial component, and an

Art Unit: 3738

intermediate insert (fig.3c), having the shape claimed, the femoral component having in a frontal plane, an undulating curve, with two convex condylar lateral parts, and a hollowed concave central portion, the intermediate insert having in a frontal plane, an undulating curve with two lateral concave cavities and a central convex projection therebetween, wherein in a sagittal plane, the components have a spiral curve. See figures 3b, 3c, and col.4, lines 44-63.

Referring to claims 13-14, Walker discloses materials for components as claimed, col.7, lines 39-51)

Referring to claims 8-9, 16-17, and 19-20, Walker has shown in a frontal plane a radius R2 connecting the central projection/central hollowed part to the cavities/condyle lateral parts in figures 3b and 3c. From the figures the radius looks constant from front to rear. And since the disclosure does not suggest changing the radius or altering it in any way, it is assumed and inherent that it is constant. Also, since the patella consists of a protrusion of one size that the hollowed central part moves along, and Walker has disclosed that the patella be in continuous formed contact throughout flexion and extension (col.1, line 24; col.2, lines 7-15, 19-22; col.4, lines 6-10, 44-63), the hollowed central part must inherently have a constant radius R2 throughout flexion/extension, if it is going to remain in continuous contact with the patella. Also since the tibial surface coincides with the femoral surface, the same is inherently so for the radius R2 on the tibial component. In addition, as incorporated by reference, Walker has disclosed modifying the radius of curvature in any plane by computer program to correspond to any patients desired size (col.4, lines 48-54).

Art Unit: 3738

Claims 7-12 and 15-21 are rejected under 35 U.S.C. 102(b) as being anticipated by Millon (FR 2 621 243, cited by applicant in IDS). Referring to claims 7, 10-12, 15, 18, and 21, discloses a knee prosthesis comprising a femoral component (1), a tibial component (2/2b), and an intermediate insert (2d), having the shape claimed, the femoral component (1) having in a frontal plane (fig.2, 6, 8), an undulating curve, with two convex condylar lateral parts, and a hollowed concave central portion, the intermediate insert (2d) having in a frontal plane (fig.2, 6, 8), an undulating curve with two lateral concave cavities and a central convex projection therebetween, wherein in a sagittal plane (fig.1), the components have a spiral curve, wherein the undulating curves have an absence of discontinuities or sharp edges (fig.3, 4).

Referring to claims 8-9, 16-17, and 19-20, Millon has shown in a frontal plane a radius R2 connecting the central projection/central hollowed part to the cavities/condyle lateral parts. From the figures the radius looks constant from front to rear.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

In the alternative to the above rejections, claims 7-21 are rejected under 35 U.S.C. 103(a) as being unpatentable over Roger et al. (US 5,935,173) in view of Walker (US 5,330,533, cited in previous office action). Referring to independent claims 7, 15, and 18, Roger discloses a knee prosthesis substantially as claimed. Roger discloses a knee prosthesis (10) comprising a femoral

Art Unit: 3738

component (11), a tibial component (12), and an intermediate insert (13), the femoral component (11) having in a frontal plane, an undulating curve, with two convex condylar lateral parts (14, 15), and a hollowed concave central portion (fig.2), the intermediate insert having in a frontal plane, an undulating curve with two lateral concave cavities (21) and a central convex projection therebetween (24; fig.2, 4, 5; col.5, lines 6-15, 18-21), wherein in a sagittal plane, the components have a spiral curve (varied radius in the sagittal plane, col.2, lines 10-16; col.4, lines 45-51; col.5, lines 6-16). Roger discloses a knee prosthesis substantially as claimed. Roger does not however, disclose the component's undulating curve extending from front to rear with an absence of any discontinuities. Walker teaches in the same field of knee prostheses, a femoral (fig.3b) and insert (fig.3c) component having an undulating curve which extends from front to rear of the articular surface, without discontinuities (fig.3b, 3c), for the purpose of increased contact area, therefore minimized stress and wear (col.4, lines 44-59). It would have been obvious to one having ordinary skill in the art at the time the invention was made to combine Walker's teaching of absence of discontinuities and edges on knee components, with Roger's knee prosthesis components, in order to provide increased contact area of the components, therefore, reducing stress and wear.

Referring to claims 10-12 and 21, Roger discloses a spiral curve in the sagittal plane for the femoral and insert components (varied radius in the sagittal plane, col.2, lines 10-16; col.4, lines 45-51; col.5, lines 6-16).

Referring to claims 8, 9, 16, 17, 19, and 20, Roger discloses a radius R2 in the frontal plane of the femoral and insert component that is constant from front to rear (col.3, lines 60-65).

Referring to claims 13-14, Roger discloses femoral and tibial components, along with the insert being formed of the materials claimed (col.4, lines 40-42, 60-64).

Conclusion

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than **SIX MONTHS** from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Cheryl Miller whose telephone number is (703) 305-2812. The examiner can normally be reached on Monday through Friday from 7:30am to 5:00pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Corrine McDermott, can be reached on 308-2111. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Art Unit: 3738

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).



Cheryl Miller



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